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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,900	06/23/2006	Francois Schutze	032013-120	5877

23911 7590 03/28/2008

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
03/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,900	SCHUTZE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 11-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 11-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed December 31, 2007 is acknowledged. Claims 1 and 11-21 remain under consideration.

Applicants' arguments have been carefully considered. Those rejections set forth in the First Office Action that are not herein reiterated are withdrawn. The following rejections constitute the only rejections presently applied to the instant claims.

Claims 1 and 11-16 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7 and 9 of copending Application No. 10/561844 in the last Office Action. Instant claim 1 encompasses a medicament comprising enantiomers of tenatoprazole. The co-pending claims additionally are drawn to an amount of active substance in the range of 10-80 mg and may be employed to treat digestive bleeding. Claims 1 and 11-21 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 14-22 of copending Application No. 11/344212 in the last Office Action. Instant claim 1 encompasses a medicament comprising enantiomers of tenatoprazole. The co-pending claims are additionally drawn to dosage forms and an amount of active substance that overlaps with those presently claimed and are employed to treat any digestive disease. Claims 1 and 11-21 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 9-18 of copending Application No. 10/532114 in the last Office Action. The co-pending claims are drawn to compositions comprising tenatoprazole to treat any disease, including symptoms and lesions, relating to gastric hyperacidity. The open language of the present claims allows for the inclusion of any number of additional active or inactive agents.

Applicants choose to hold these provisional obviousness-type double patenting rejections in abeyance.

In the last Office Action claims 1 and 11-21 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-10 and 14-25 of U.S. Patent 7,034,038. Instant claim 1 encompasses a medicament comprising enantiomers of tenatoprazole. The claims additionally are drawn to dosage forms and an amount of active substance that overlap with those presently claimed and are employed to treat any digestive disease.

Applicants choose to hold this obviousness-type double patenting rejection in abeyance.

All obviousness-type double patenting rejections set forth *supra* are maintained.

In the last Office Action claims 1 and 11-21 were rejected under 35 U.S.C. 102(e) as being anticipated by Barth et al., US 2006/0024238. It was asserted Barth teaches the administration of one proton pump inhibitor, such as tenatoprazole, or a pharmaceutically acceptable salt thereof, in the treatment of atypical and esophageal symptoms of gastroesophageal reflux disease (GERD). Barth's teaching encompasses, *inter alia*, treating Barrett's esophagus, horseness, wheezing, coughing and asthma. See paragraphs [0009] and [0010], page 2, [0029], page 4, and [0044] page 5, and claims 9, 12-14, pages 13-14. Barth teaches equivalence among the proton pump inhibitors in methods of treating GERD. Dosages, as required by instant claims 11, 15 and 16, are taught to be preferably about 10-30 mg per day, in paragraph [0091], page 9. As required by instant claim 14, injectable preparations are disclosed in paragraph [0096], page 9. Medicaments comprising proton pump inhibitors for oral administration are disclosed in paragraph [0097] on page 10.

Applicants argue Barth does not recite each and every element of the presently claimed invention.

Barth teaches compositions comprising tenatoprazole wherein the amount of the proton pump inhibitor is preferably a dosage form having about 0.1 to about 40 mg of tenatoprazole to be given daily. See page 9, paragraph [0091], and page 14, claim 18. Treatment is directed to Barrett's esophagus or dyspepsia. See page 2, paragraph [0009]. Administration may be oral or parenteral. See page 9, paragraphs [0095], and [0096]. See page 2, paragraph [0009], where the gastrointestinal disorders contemplated by Barth may be dyspepsia or reflux, in addition to Barrett's esophagus. The treatment of gastroesophageal reflux disease includes nocturnal reflux. Atypical symptoms are disclosed and encompassed in Barth's teaching on page 4, paragraph [0029], and page 5, [0044]. See page 10, paragraph [0098], where it is stated sodium bicarbonate can be formulated or admixed with the proton pump inhibitor to form a medicament.

Accordingly, each element of the presently claimed invention is disclosed. The rejection of record under 35 U.S.C. 102(e) is maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory

period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 21, 2008

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614